IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **WAVE 1 CASES**	**Master File No. 2:12-MD-02327** **MDL No. 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' OPPOSITION TO
DEFENDANTS' MOTION TO EXCLUDE
CERTAIN OPINIONS OF MICHAEL THOMAS MARGOLIS, M.D.

Dr. Michael Thomas Margolis, M.D. is one of a small number of American physicians board-certified in the obstetrics and gynecology subspecialty of Female Reproductive Surgery. He is among the nation's foremost experts in explanting synthetic mesh, has studied and lectured extensively on the causes and effects of mesh device failure, and has testified to the FDA on the issue. This Court has previously recognized Dr. Margolis's qualifications to testify in another pelvic mesh proceeding. *In re Ethicon, Inc., Pelvic Repair System Products Liab. Litig.* ("*Lewis*"), 2014 WL 186872, at *17 (S.D. W.Va. Jan. 15, 2014) (admitting opinions on effectiveness of TVT). Likewise here, Dr. Margolis is well qualified to offer the opinions on the TVT and TVT-O devices that Defendants seek to exclude.

Moreover, despite Ethicon's efforts to mischaracterizations Dr. Margolis' testimony, it is clear that Dr. Margolis applied a reasonable methodology – including relying on his extensive experience, together with a review of scientific data, medical literature, and Ethicon's internal documents – to arrive at his opinions. *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 156 (1999) (experts are permitting to draw conclusions based on their extensive and specialized

experience). Dr. Margolis's adherence to this bedrock approach to expert testimony has produced reliable and relevant opinions that should be admitted to aid the jury.

Plaintiffs will not offer Dr. Margolis for expert opinions related to Prolift, the risks of cancer from TVT or TVT-O, or product marketing. In all other respects, Ethicon's Motion to Exclude Certain Opinions of Dr. Margolis should be denied.

LEGAL STANDARD

Federal Rule of Evidence 702 sets forth the basic framework for analyzing the admissibility of expert opinions:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

If the witness is suitably qualified, then the *Daubert* inquiry generally breaks down into a two-step analysis. The first issue is whether the proffered evidence represents "scientific knowledge," meaning that it is supported by appropriate validation. The second issue is whether the evidence would assist the jury. *United States v. Dorsey*, 45 F.3d 809, 813 (4th Cir. 1995). This aspect of the inquiry is often discussed in terms of whether the expert's opinions "fit" the case. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 591-92 (1993).

In *Daubert*, the Supreme Court emphasized that "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id. at* 596.

ARGUMENT

I. Dr. Margolis's Qualifications and Methodology

A. Dr. Margolis is highly qualified to put forth the opinions offered on the TVT and TVT-O devices.

As this Court has succinctly acknowledged, "Dr. Margolis is a pelvic surgeon and a urogynecologist with experience implanting and removing [SUI] sling systems." *Lewis*, 2014 WL 186872, at *15. He is Board-Certified by the American Board of Obstetrics and Gynecology. Ex. C to Defendants' brief ("Def. br.") at 2.[1] Dr. Margolis is a fellow in good standing of the American College of Obstetrics and Gynecology, the American College of Surgeons, and the Society of Pelvic Reconstructive Surgery, among other organizations. *Id.* Recently, Dr. Margolis passed the first subspecialty board certification examination in the subspecialty of Female Pelvic Medicine and Reconstructive Surgery, becoming the first member of the first class of board-certified pelvic surgeons in the country. *Id.*

Dr. Margolis currently maintains an active pelvic and urogynecological surgical practice in California. *Id.* at 4. He serves as the District VII delegate to the California Medical Association. *Id.* at 2. Dr. Margolis estimates that he has performed over 25,000 surgical procedures in his practice of pelvic surgery and urogynecology. *Id.* at 4. Approximately 1,500 of those procedures involved the use of organic vaginal slings. *Id.* Since 1996, Dr. Margolis has removed over 300 mesh or sling systems from patients who have suffered complications. *Id.* at 4-5. Patients are referred to Dr. Margolis from around the country, and he now removes an average of two vaginal mesh systems per week from women experiencing complications. *Id.*

Dr. Margolis has authored numerous publications in the field of obstetrics and gynecology and has written several book chapters in the field. *Id.* at 3. He has lectured

[1] As Defendants point out, Dr. Margolis's general report on TVT (Def. br. at Ex. C) is essentially identical to his general report on TVT-O (Def. br. at Ex. D). *See* Def. Br. at 3 n.2.

extensively throughout the United States and abroad on topics involving vaginal mesh complications and advanced pelvic surgery, including the treatment of prolapse and incontinence. *Id.* at 3. He has even testified, at the request of the FDA, on the complications of transvaginal mesh placement. *Id.* at 4.

Additionally, Dr. Margolis has observed numerous sling insertion procedures by colleagues and through industry videos, including procedures involving Defendants' TVT products. *Id.* at 5. He has studied textbooks, publications and IFUs, including those for the TVTs, surgical videos, cadaver dissections, and operative reports as part of his study of sling and mesh surgeries. *Id.* He has also conferred with colleagues in the United States and abroad on the subject. *Id.*

Dr. Margolis has also performed animal testing on many novel surgical instruments and field testing in humans for Boston Scientific sling anchor instruments. *Id.* at 3.

The Court acknowledged these, and other, qualifications and experiences by Dr. Margolis in a prior pelvic mesh proceeding:

> Dr. Margolis is qualified to comment on the effectiveness of the TVT. He has explanted over 200 mesh slings, including the TVT device. He has additionally observed "numerous" sling and mesh procedures involving TVT products and studied "textbooks, publications, IFU[ ]s (including those from J & J/Ethicon for the TVTs), surgical videos, cadaver dissections and countless operative reports...." I therefore FIND that Dr. Margolis's opinions related to the effectiveness of Ethicon's TVT should not be excluded.

Lewis, 2014 WL 186872 at *17 (record citations omitted). The same conclusion, that Dr. Margolis is amply qualified to testify regarding the TVT and TVT–O, should follow here.

B. Dr. Margolis has applied an accepted and reliable methodology to arrive at his opinions.

Dr. Margolis formulated his general opinions in this case based on his personal experience explanting meshes, his study of medical literature, and a review of Ethicon's internal

documents, depositions of Ethicon employees, and other expert reports. *See* Ex. C to Def. Br. at 5, 7, 9-10. The methodology Dr. Margolis followed in arriving at his opinions is akin to the methodology he used when the FDA called him to testify "on the serious issue of complications of transvaginal synthetic mesh placement." *Id.* at 4. Dr. Margolis' FDA testimony "was based on [his] knowledge, experience, education, and training as a pelvic surgeon and on observations made during scores of salvage operations [performed] on women who have experienced mesh and sling complications since 1996." *Id.* These are accepted and reliable techniques for arriving at expert opinions.

II. Defendants' motion to exclude opinions that go to Defendants' knowledge, state of mind, or alleged bad acts is overbroad.

Plaintiffs are aware that this Court has previously held that experts may not testify as to a party's knowledge, state of mind, or whether a party acted reasonably. *See, e.g.*, *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *3 (S.D. W. Va. May 5, 2015). The Court has declined, however, to parse through the numerous reports and depositions for each expert to determine the validity of every such objection. *Id.*; *see also Edwards v. Ethicon, Inc.*, No. 2:12-c-09972, 2014 WL 3361923, at *13 n.3 (S.D. W. Va. July 8, 2014) ("As I previously stated, I will not parse expert reports in relation to this objection.") Rather, the Court has acknowledged that the issue is appropriately addressed at trial: "The onus is on counsel to tailor expert testimony at trial in accordance with the above directive." *Wilkerson*, 2015 WL 2087048, at *3. The Court should follow its prior rulings and let the trial judges address the issue.

That approach is particularly fitting here, where Defendants' motion seeks to exclude more than state-of-mind testimony. *See* Def. Br. at 3-4. Dr. Margolis does not intend to testify about Ethicon's hidden motives or secret intentions. However, he should not be precluded from

relying on documentary evidence and the testimony of Ethicon's executives as to what information was available to Ethicon at a given time, in forming his opinions. In particular, Defendants cite to several opinions of Dr. Margolis that go to the inadequacy of Defendants' warnings. Dr. Margolis should be permitted to testify on that issue, as discussed in Section III, *infra*.

Defendants' suggestion that Dr. Margolis merely reviewed documents that Plaintiffs' counsel "selectively presented to him" is unfounded. *See* Def. Br. at 4. As Dr. Margolis has previously testified, his approach is to ask for "all records, both good, bad, and indifferent, so that I can provide a balanced, objective, medical opinion." July 19, 2015 Margolis Dep. (*Cavness*), Exhibit A attached, at 44:6-45:1. Dr. Margolis highlights specific Ethicon documents and testimony in his reports because they support his opinions. *See, e.g.*, Def. Ex. C at 9 n.2 (regarding undisclosed risks); 10 n.4 (citing internal document inconsistent with IFU and his own experience); 10-11 n.6-8 (Ethicon testimony and studies on mesh degradation). Even Defendants acknowledge that an expert "may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions." Def. Br. at 5 (quoting *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W.Va. 2013)).

To the extent that Dr. Margolis's opinions are otherwise proper and admissible, they should not be entirely excluded simply because he may have used language in his reports that could be construed as a corporate state of mind. While strict "state of mind" testimony may be excluded, any substantive testimony should be allowed at trial.

III. Dr. Margolis should be permitted to testify as to the inadequacy of Defendants' product warnings.

Defendants assert that Dr. Margolis should not be permitted to testify on product warnings because he is not an expert on the legal requirements of medical device warnings. The

argument is misplaced. Dr. Margolis will not opine as to whether the TVT and TVT-O labeling conformed to FDA requirements. Dr. Margolis is qualified, however, to testify about the risks he perceives (as a pelvic surgeon) from the devices and whether the IFUs for the devices adequately conveys those risks. His opinions are also reliable, in that they are based on his extensive education and professional experience, the consideration of voluminous medical literature, and a review of Ethicon's internal documents.

A. Dr. Margolis is qualified to offer opinions on the warnings Defendants provided to physicians.

It is well recognized that "whether or not a given warning is adequate depends upon the language used and the impression that it is calculated to make upon the mind of an average user of the product." *See Robertson v. Norton Co.*, 148 F.3d 905, 907 (8th Cir.1998). Accordingly, this Court and numerous others recognize that doctors are well-qualified to opine on the risks of the product as compared to the information disclosed in the labeling. *See, e.g., Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *5 (S.D. W. Va. Feb. 7, 2015) (holding that Dr. Ostergard, a urologist, was qualified to evaluate the warnings for a pelvic mesh device based on his knowledge of and clinical experience with such products); *Huskey v. Ethicon, Inc.*, No. 2:12–cv–05201, 2014 WL 3362264, at *34 (S.D. W. Va. July 8, 2014) (finding Dr. Blaivas, a urologist, qualified to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU); *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings ....") (internal quotations and brackets omitted); *Rebecca Dion, v. The Graduate Hospital of the Univ. of Pennsylvania, et. al.*, No. 2841, 1986 WL 501497 (Pa. Com. Pl. Feb. 28, 1986) (because

warnings are directed at physicians, physicians or those with similar education and experience are well qualified to determine whether a medical product's warning is adequate); *Calisi v. Abbott Laboratories*, No. 11-10671, 2013 WL 5441355, at *7, 8-9 (D. Mass. September 27, 2013) (suggesting that a doctor would be the proper source for testimony that the label failed to "provide adequate information to doctors would be helpful to the jury"); *Stahl v. Novartis Pharmaceuticals Corp.*, 283 F.3d 254 (5th Cir. 2002) (allowing treating physician to testify as to whether drug label adequately informed him of known risks).

In *Wilkerson*, this Court specifically recognized that a lack of experience regarding the legal requirements for medical device warnings does not preclude a physician from testifying on the adequacy of the product's warnings:

> [A urogynecologist who] has no demonstrated experience in the requirements for medical device labels cannot testify as to what the [product] label should or should not have included under the law. However, as an experienced urogynecologist, he may testify about the risks he perceives that the [product] poses to patients and then opine that the [product's DFU] did not convey those risks. *See In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings…." (internal quotations and brackets omitted)).

Wilkerson, 2015 WL 2087048, at * 8 (citing *Wise v. C.R. Bard, Inc.*, No. 2:12-cv-01378, 2015 WL 521202, at *14 (S.D. W. Va. Feb. 7, 2015)).

That reasoning applies here. Dr. Margolis is fully qualified to testify as to what information a pelvic surgeon would need to have, and would consider, when deciding whether to use a TVT or TVT-O to treat a particular patient. Dr. Margolis's 25 years of professional experience render him uniquely qualified to testify *from a doctor's perspective* as to how information contained on the label is viewed, interpreted and used by physicians and whether particular omitted information would be material to a physician's treatment decisions.

Defendants' complaint that Dr. Margolis has not drafted an IFU is misplaced. Dr. Margolis is familiar with IFUs because he uses them every day in his medical practice. *See* Nov. 25, 2013, Margolis Dep. (*Lewis*), attached as Exhibit B, at 7:11. He also uses them regularly in his teaching and lectures to residents, fellows, and attending physicians throughout the country. *Id.*

Defendants point to *In re C.R. Bard,* in which the Court precluded Dr. Bob Shull from testifying about product warnings. *See* Def. Br. at 5 (citing *In re: C.R. Bard, Inc.*, 948 F. Supp. 2d 589 (S.D. W.Va. 2013)). That ruling is inapposite. Dr. Shull admitted that he had not developed product warnings, had no experience in that area, and did not hold himself out as an expert in product warnings. *See Bard,* 948 F. Supp. 2d at 611. Dr. Rosenzweig, in contrast, made no such admissions, and the Court found him qualified to testify about TVT-O's product warnings and marketing materials. *See Edwards*, 2014 WL 3361923, at *8 & n.2.

Similar to Dr. Rosenzweig, Dr. Margolis has made no admission that he is not qualified to testify about TVT or TVT-O product warnings. While he may not be experienced in the legal requirements for medical device labels, Dr. Margolis is qualified to "testify about the risks he perceives that [the TVT and TVT-O] pose[] to patients and then opine that the [products' IFU] did not convey those risks." *See Wilkerson,* 2015 WL 2087048, at *8.

B. Dr. Margolis's opinions are reliable.

While Defendants make the sweeping assertion that "many" of the complications Dr. Margolis cites on pages 7-8 of his reports have not been reliably attributed to TVT, the only specific complications they take on are degradation and the risk of cancer. *See* Def. Br. at 8-9. Dr. Margolis will not offer opinions on whether the mesh causes cancer. As for degradation, Dr. Margolis has disclosed the extensive medical literature on which he relied in forming his

opinions. *See* Ex. C& D to Def. Br. at 31-92. Dr. Margolis also relied on his extensive education and experience as well as Ethicon's internal documents in forming his opinions. Defendants did not even depose Dr. Margolis on the opinions in his general reports in this case. The fact that Dr. Margolis could not point to a specific study in a deposition in a prior case is not fatal to the admissibility of his opinions. *See, e.g.*, *Wise*, 2015 WL 521202, at *15 ("[G]iven that Dr. Raybon has demonstrated in his report that his opinions have literary support, I decline to exclude his opinions on the grounds that he was unable to recall the literature during his deposition").

The *Daubert* inquiry is flexible, and "not being able to cite a specific medical literature at a deposition [does] not disqualify an expert as 'unreliable'…." *Qeisi v. Patel*, No. 02-8211, 2007 WL 527445, at *8 (E.D. Pa. Feb. 9, 2007). In *Qeisi*, the court denied the defendant's *Daubert* motion on this basis, taking into account the physician's expert report, which discussed medical literature as well as his education and extensive experience in his field. As the *Qeisi* court succinctly stated: "'Gotcha' advocacy…will not carry the day." *Id.* at *7.

Defendants note that in a deposition in *Batiste*, Dr. Margolis could not point to clinical literature that degraded polypropylene mesh increases the inflammatory response. However, a study by the Long Beach Medical Center and the University of Louisville, which included TVT and on which Dr. Margolis relies,[2] describes that inflammation-degradation cycle:

> [T]here is an immune response in the acute inflammatory phase, followed by the secretion of acid by macrophages, which attacks the mesh and starts the oxidative process already begun by the heat of the manufacturing process. The [polypropylene] degradation that follows releases additives in the [polypropylene] that enhance the inflammatory response.

Sternschuss, G., et al., *Post-Implantation Alterations of Polypropylene in the Human*, J. of Urol. at 31 (2012), attached as Exhibit C.

[2] *See* Margolis List of Materials Reviewed at 6 (Exs. C & D to Def. br. at 36).

Similarly, the fact that Dr. Margolis is not aware of any mesh degradation particles that are found in other places besides the vaginal canal does not render his opinions on mechanically cut mesh unreliable. *See* Def. Br. at 8 & Ex. F to Def. br. at 206:19-22. In his reports, Dr. Margolis discusses the particle loss, fraying, roping, deformation, and degradation that occurs with mechanically cut mesh and cites, in part, to Ethicon's own documents in support of his opinions. *See* Ex. C to Def. Br. at 16-18. He further explains the many adverse events that result, including chronic debilitating pain, difficulty urinating, painful sex, erosions, the need for mesh removal including multiple additional surgeries, and urinary incontinence. *See id.* at 17-18.

The case on which Defendants rely, *Johnson & Johnson v. Batiste*, 2015 WL 6751063 (Tex. App. Nov. 5, 2015) (review filed Dec. 18, 2015), has no application here. That case was on appeal following a jury verdict in the plaintiff's favor. The appellate court reversed the verdict for insufficient evidence on specific causation. *Batiste*, 2015 WL 6751063, at *11 (concluding that plaintiff failed to produce more than a scintilla of evidence that any alleged defect caused her injuries). The court found, "there is no evidence as to the amount of degradation that must occur before it has any clinical significance in a patient, *and* there is no evidence the mesh that was placed inside of Batiste had degraded to the extent that it caused her injury." *Id.* at *8 (emphasis added). The case is currently on appeal.

Nevertheless, the instant motion presents no issue of specific causation. Moreover, Dr. Margolis has made no admission like that of Batiste's expert that there could be degradation that would have no clinical significance to a patient. *See Batiste*, 2015 WL 6751063, at *6. To the contrary, Dr. Margolis testified in *Batiste* that the degradation that occurs with the TVT has clinical significance. Ex. F to Def. Br. at 205:20-25. He elaborated as follows: "There are

internal documents that I've reviewed, and there are the clinical correlates to what has been described in the internal documents of mesh as it has protruded through the vagina after having been broken down." Ex. F to Def. Br. at 205:12-19. Further, Dr. Margolis describes in this expert reports the relationship between the degradation of mesh and chronic foreign body response. *See, e.g.*, Ex. C to Def. Br. at 10-12 (discussing degradation and citing internal documents, medical literature, and his own professional experience).

This Court's ruling in *Wilkerson* is directly on point. The Court allowed Dr. Rosenzweig to testify on the complications association with mesh degradation. *See Wilkerson*, 2015 2087048, at *5. Similar to Dr. Margolis, Dr. Rosenzweig has performed over 1,000 pelvic floor surgeries and close to 300 surgeries dealing with mesh implant complications. *Id.* The Court explained, "Dr. Rosenzweig's established background and skill in pelvic surgery, polypropylene, and the complications associated with degradation qualify him to opine on the degradation process, even though his knowledge about the precise biochemical interactions involved might not be as extensive as that of others." *Id.*

Likewise, the Court should allow Dr. Margolis to testify as to degradation complications here. Dr. Margolis reached his opinions on mesh degradation based on his professional education and experience, including performing hundreds of mesh explant surgeries, studying medical textbooks and publications, as well as reviewing Ethicon's internal documents and employee testimony. Reviewing internal documents and scientific literature, and relying on one's education and experience, is a reliable method of forming opinions. Dr. Margolis's opinions on degradation should, therefore, be admitted.

IV. As in *Lewis*, Defendants' documents provide factual bases for Dr. Margolis's opinions and are not "mere historical commentary."

Defendants assert that certain statements from Dr. Margolis's reports should be excluded as merely historical narrative. The Court rejected this argument in *Lewis* and should do likewise here. *See Lewis*, 2014 WL 186872, at *16 (permitting testimony on internal documents as factual support for opinions).

It is well establish that while an expert may not simply narrate corporate documents in front of the jury, an expert may rely upon information contained in corporate documents to reach and support his opinion. *See, e.g., Wise v. C.R. Bard, Inc.*, No. 2:12-CV-01378, 2015 WL 521202, at *15 (S.D.W. Va. Feb. 7, 2015) (allowing expert to use and rely on internal documents to develop and reinforce his opinions); *Sanchez v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *4 (S.D. W. Va. Sept. 29, 2014) (an expert may testify about his review of internal corporate documents for the purpose of explaining the basis for his opinions); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 722 (S.D. W. Va. 2014) (admitting expert opinions regarding complications of a particular surgical approach that were based on defendant's internal documents) ("I FIND that Dr. Blaivas' opinions are not unreliable simply because he relied on internal Ethicon documents.); *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F.Supp.2d 1348, 1368 (M.D. Ga. 2010) ("[T]he experts' reliance on the journal articles and [the defendant's] internal documents does not diminish the weight that the Court gives to the experts' opinions).

Not only did Defendants raise this same argument against Dr. Margolis in *Lewis*, they even seek to exclude some of the same testimony. *See Lewis*, 2014 WL 186872, at *16 (citing Margolis testimony regarding Ethicon's lack of "procedure or Professional Education program to teach doctors how to properly remove slings when known complications occurred" and

"inadmissible hearsay" of manufacturers of polypropylene resin). The Court rejected the argument in its entirety, explaining: "These statements provide the factual basis for Dr. Margolis's opinions and are therefore helpful for the jury to understand Dr. Margolis's opinions." *Id.* The Court further held: "if Ethicon contends that certain statements are inadmissible hearsay, it may object to them at trial. A *Daubert* motion is not the proper method of excluding hearsay." *Id.*

The Court should hold likewise here. As is evidenced throughout his reports, Dr. Margolis relies on Defendants' internal documents to inform and support his opinions. And any hearsay objections are properly made at trial. Defendants' motion should be denied on this issue.

V. Dr. Margolis's opinions related to the propriety of the TVT and TVT-O are grounded in reliable bases.

This Court has previously found Dr. Margolis qualified to testify on the effectiveness of the TVT and should do so here. *See Lewis*, 2014 WL 186872, at *17. Defendants seek to exclude cherry-picked opinions of Dr. Margolis on this issue, because he did not identify specific studies when asked in prior depositions. Again, this is not an appropriate basis to exclude expert testimony. *See Wise*, 2015 WL 521202, at *15. Dr. Margolis has disclosed in his reports the medical literature on which he relied in forming his opinions.

There is medical literature, for example, which supports Dr. Margolis's conclusion that the Burch procedure is the preferred method of treatment for stress urinary incontinence. Te Linde's Operative Gynecology describes the Burch or MMK procedure as the "gold standard":

> The gold-standard surgical treatment of SUI in patients with a mobile bladder neck and normally functioning urethra has been accomplished through a retropubic approach using either a Burch retropubic urethropexy or Marshall-Marchetti-Krantz (MMK) procedure.

John A. Rock, MD, & Howard W. Jones III, MD, Te Linde's Operative Gynecology (10th ed. 2011), at 943-44, attached as Exhibit D.[3] Dr. Rebecca Rogers likewise wrote in the New England Journal of Medicine, "[a]lthough more than 100 surgical procedures have been described for the treatment of stress incontinence, gold-standard procedures include the Burch polposuspension and the fascial sling." Rebecca Rogers, MD, "Urinary Stress Incontinence in Women," N. Engl. J. Med. 1029, 1033 (2008), attached as Exhibit E.[4] Defendants are quick to point out that Dr. Margolis acknowledges there are studies that describe mid-urethral slings as the "gold standard." He should be allowed to counter that testimony with his opinion that the Burch/MMK is the gold standard.

There is also medical literature to support Dr. Margolis's opinion that the TVT is no more efficacious at treating stress urinary incontinence than other procedures that do not involve mesh. *See* Ex. C to Def. br. at 25. For example, Te Linde's Operative Gynecology reported cure rates of 93% and 88% for laparoscopic Burch and open Burch, respectively, while efficacy reports for TVT were in the "85% range." John A. Rock, M.D., & Howard W. Jones III, M.D., Te Linde's Operative Gynecology (10th ed. 2011), at 944 & 950, Ex. D.

Dr. Margolis opines that the Prolene mesh used in TVT products is not suitable for implantation in the vagina. Ex. C to Def. Br. at 11. That is consistent with the testimony he gave to the FDA in which he expressed his opinion that polypropylene mesh like TVT should be pulled from the market. Margolis *Batiste* Dep., Ex. F to Def. br., at 118:9-16. These conclusions cannot seriously be deemed unreliable, given that the manufacturers of polypropylene themselves have warned that the material should never have been permanently implanted in the

[3] *See* Margolis List of Materials Reviewed at 7 (Exs. C & D to Def. br. at 37).
[4] Exs. C & D to Def. br. at 50.

human body. *See* Ex. C to Def. br. at 19-20 (discussing Material Safety Data Sheets of Phillips Sumika and Chevron Corporation).

At bottom, Defendants' challenges here go to the weight of Dr. Margolis's testimony, and not its admissibility. To the extent Defendants wish to question the bases of Dr. Margolis's opinions, the issue is appropriately addressed at trial on cross-examination. *See, e.g.*, *Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004) ("[A]s a general rule, questions relating to the bases and sources of an expert's opinion affect the *weight* to be assigned that opinion rather than its *admissibility* and should be left for the jury's consideration.") (quoting *United States v. 14.38 Acres of Land, More or Less Situated in Leflore County*, 80 F.3d 1074, 1077 (5th Cir.1996)).

VI. Dr. Margolis is qualified to opine about the biomaterial properties of mesh.

Dr. Margolis will readily admit that he is not a "biomaterials" expert. As such, he will not be conducting biomaterial testing or attempting to explain the precise biomaterial processes that occur when polypropylene degrades. He will, however, be testifying about how the characteristics of the TVT and TVT-O influence their clinical performance based on his extensive knowledge and experience as a pelvic floor surgeon. For example, Dr. Margolis may touch upon mesh pore size; but he will not offer a scientific analysis of mesh design properties. Rather he will discuss pore size in the context of what he has seen and considered as a practicing surgeon experienced in removing mesh slings: that the porosity shrinks as the mesh becomes enveloped in scar tissue. In this context, any biomaterial testing data and medical literature referenced by Dr. Margolis would be intended to confirm and support what he was seeing in his clinical practice.

Under Federal Rule of Evidence 702, "[o]ne knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). A court may not exclude testimony "simply because it does not deem the proposed expert to be the best qualified or because the expert does not have the specialization that the court considers most appropriate." *Pineda v. Ford Motor Co.*, 52 F.3d 237, 244 (3d Cir. 2008). In short, the test for exclusion is strict. *Lorillard*, 878 F.2d at 799.

This Court's prior rulings bear that out, and support the admission of Dr. Margolis's testimony regarding the characteristics and design of mesh. *See Wilkerson*, 2015 WL2087048, at *5-6 (permitting urogynecologist to opine on mesh degradation and the properties of polypropylene); *Wise*, 2015 WL 521202, at *15 (ob/gyn with extensive experience in pelvic reconstruction surgeries qualified to opine about the design of mesh, including the characteristics of polypropylene).

Again, Dr. Margolis has performed over 1,500 pelvic mesh surgeries and over 300 explant surgeries involving patients with mesh complications. He has observed numerous sling insertion procedures, including those involving TVT, and has studied and lectured extensively on the causes and effects of mesh device failure. He is also a published author and has testified to the FDA on the subject. Additionally, Dr. Margolis has performed animal testing on surgical instruments and field testing on humans regarding sling anchor instruments of Defendants' competitor, Boston Scientific. In sum, Dr. Margolis is qualified to testify on the biomaterial properties and design of the TVT and TVT-O devices.

VII. Dr. Margolis may use metaphors that are helpful to the jury.

Defendants seek to exclude testimony of Dr. Margolis in which he has used metaphors to help explain his opinions. Defendants do not cite to a single case in support of their argument that such testimony should be excluded. In fact, other courts have approved the use of analogies by experts as testimony that is helpful to understanding the issues. *See, e.g.*, *Astrazeneca LP v. Mylan Pharmaceuticals Inc.*, No. 08-453-GMS, 2011 WL 2516381, at *5 n.8 (D. Del. June 23, 2011) (finding metaphors helpful in understanding technical processes in pharmaceutical manufacturing); *Fitzgerald v. Trammell*, No. 03-cv-531-GKF-TLW, 2013 WL 5537387, at *38 (N.D. Okla. Oct. 7, 2013) (describing expert's image of a cart rolling downhill as "teaching metaphor" to understanding criminal defendants' decision-making processes).

In *Astrazeneca LP v. Mylan Pharmaceuticals Inc.*, both plaintiff's expert and defendant's expert used metaphors in testifying in a patent infringement case. No. 08-453-GMS, 2011 WL 2516381, at *5 n.8 (D. Del. June 23, 2011). At issue was whether the lactose particles in Mylan's product were completely coated with a layer of budesonide/ethylcellulose, which would infringe on Astrazeneca's Entocort patent, or were merely connected by the ethylcellulose, which would not. *Id.* at *3-4. In a bench-tried case, Mylan's expert analogized the ethylcellulose to pasta, which has a tendency to hydrate, swell and eventually clump together when overcooked. Astrazeneca criticized the testimony, claiming it was unsupported by any experimental results or scientific observations. *Id.* at *5 n.8. The court dismissed the argument, and noted that in explaining the function of a disintegrant in Mylan's product, Astrazeneca's own expert used the metaphor of a "little time bomb" that "blows up." The court found both analogies "beneficial in helping it understand the technical processes that the experts were describing." *Id.*

Likewise here, Dr. Margolis's analogies would be beneficial in helping a jury understand the technical aspects of the polypropylene mesh and its resulting complications. Contrary to Defendants' assertion, the volcano analogy refers to the defective mesh, not to the patient's vagina. *See* Def. br. at 16. Like the time bomb analogy in *Astrazeneca* case, the analogy is apt, as are the analogies of particle loss in the body to shards of glass on the floor and explant surgery to removing rebar from cement. Dr. Margolis used the broken glass analogy for the jury in the *Batiste* trial.

Further, Dr. Margolis uses the concrete analogy to highlight the harsh reality of what the mesh was designed to do:

> …as with all meshes, their job – what they are designed to do is to set up an inflammatory reaction, which causes the immune system to attack, and then eventually causes scar tissue to come in and set it in place.
>
> That's the purpose of the mesh. That's why it's – it doesn't require stitches to hold it in place. That scar tissue set it in place. That's what all of these meshes are designed to do.
>
> But the scar tissue, once it forms over the mesh – again, it's like the old analogy I used before, rebar, it's set in place and it locks it into – the fibrosis locks the mesh into place.

Margolis Dep. (July 26, 2015) (*Rabiola*), Ex. J to Def. br., at 156:4-22. In addition to prior cases, Dr. Margolis used the analogy in 2011 in testifying at the FDA hearing for the Obstetrics and Gynecology Devices Panel on complications of transvaginal synthetic mesh placement. *See* Ex. C to Def. Br. at 4. It can hardly be deemed "extreme" to describe the consequences of what Defendants themselves intended to occur from the mesh.

Defendants themselves are no strangers to the use of analogy. Kevin Mahar, U.S. Group Product Director, wrote in an internal exchange on mechanically-cut mesh, "While we would work with our agency to get this right, my thoughts are that we KEEP selling regular TVT (the

Colonel's 'Original Recipe') to those customers that want/love it." ETH.MESH00687819-822, attached as Exhibit F (emphasis and internal quotations in original). He thus likened the device intended for permanent implantation in a woman's body to a piece of fried chicken.

VIII. A blanket prohibition on testimony under Fed. R. Evid. 26(a)(2)(B) is not proper on a motion to exclude.

Defendant seeks to exclude opinions of Dr. Margolis that are not set forth in his expert reports or supported by information disclosed in his reliance list. Def. Br. at 17. However, Defendants do not identify a single such opinion. Defendants' motion should be denied because they are merely asking the Court to follow Federal Rule 26(a)(2)(B). Should the issue arise at trial, it is properly addressed by the trial court at that time.

CONCLUSION

Defendants' Motion to Exclude Certain Opinions of Michael Thomas Margolis, M.D., should be denied for the reasons set forth above.

Dated this 9th day of May, 2016.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 9, 2016, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Thomas P. Cartmell

Jeffrey M. Kuntz